

REMARKS/ARGUMENTS

Telephone Interview Summary

A telephone interview was conducted with the Examiner on 25 September 2009. The discussion centered on wording that would better define the relationship between the guidewire and the working head when the working head is advanced to the distal end of the imaging guidewire.

In the Claims

Claims 1-31 remain in this application. Claims 1 and 16 have been amended. New claims 33-37 have been added.

§ 103 Rejections

The Examiner has rejected claims 1-31 under 35 U.S.C. 103(a) as being unpatentable over combinations of Hastings et al. (US2002/0019644), McKenzie et al. (5,993,469), Patel et al. (US2000/0077642), Findlay (6,623,495), Masch (4,728,319) and Chornenky et al (US5,582,171). The Examiner's rejections are respectfully traversed.

Applicant relies on arguments presented in previous papers regarding the differences between the present invention and the cited prior art of McKenzie et al., Patel et al., Findlay, Masch and Chornenky et al.

Regarding Hastings et al, Applicant understands the Examiner's point regarding the imaging guidewire of Hastings being able to be positioned so as to partially extend in front of Hastings' working head. However, Applicant asserts that such a deployment would be extremely difficult to achieve and virtually impossible to maintain during operation of the working head. This is because the diameter of the Hastings guidewire is the same throughout is full length, or at least in the region of the tip as clearly shown in Figure 5. Further, in paragraph [0048] Hastings teaches that,

"...FIG. 5 shows an embodiment of the invention wherein thermal catheter 10 has a distal tip 70 which has a tube 71 that has an open lumen 72 which communicates to the proximal end of the device. This lumen 72 can be used for several purposes. For example, the lumen can accommodate either an imaging wire 76, ultrasonic or

laser imaging, or a guide wire 74. In operation the preferred ultrasonic imaging wire can be used to visualize and locate the occlusion. Once the occlusion has been located and characterized, the correct amount of power can be delivered to the distal tip 70. Typically the ultrasound imaging wire would be withdrawn and parked in lumen 72 proximally to prevent heat damage to the transducer of the imaging wire. During device placement the lumen can be used with guide wire 74 to access the treatment site....” (emphasis added)

Therefore, Hastings is teaching the use of a guide wire during placement of the device, which would mean that the distal tip of the guide wire is position well beyond the distal end of the catheter. Once the catheter is in place, the guide wire is withdrawn such that the distal tip passes completely through the working head and catheter body and the imaging wire is deployed by having its distal tip pass completely through the catheter body and working head. This clearly shows that the distal tips of both the guide wire and the imaging wire of Hastings are able to freely past through the full length of lumen 72.

Applicant asserts that there is neither hint nor suggestion in Hastings, the other cited prior art or the prior art in general that there would be any advantage or benefit in providing an imaging guidewire such that at least a portion of the distal tip has a diameter that is larger than a rest of the guidewire which has a smaller diameter.

This is in contrast to the teaching of the present invention, which clearly teaches in Figures 1, 5, 6 and 15, and on page 8, lines 10-13,

“...An additional technical advantage of the non-crossing the lesion imaging guidewire lies in the fact that the distal tip can be relatively large. This eases the incorporating of an imaging sensor in the distal tip. For example the distal tip of this invention can be 800 microns in diameter, while the rest of the guidewire is 350 microns in diameter...” (emphasis added)

Further, Applicant would like to point out that as recited above, Hastings clearly teaches the use of both a guide wire and an imaging wire which are interchangeably deployable, such that the wire not in use is withdrawn from the catheter.

This, too, is in contrast to the teaching of the present invention, which teaches the use of a single imaging guidewire that is incapable of being withdrawn from the catheter by passing completely through the working head and catheter body.

Further, Applicant points out that Hastings is unable to providing imaging with the imaging wire withdrawn and parked in lumen 72 proximally. Therefore, redeployment of the imaging wire is necessary in order to again provide imaging capabilities.

This is also in contrast to the teaching of the present invention, which clearly teaches that once the catheter has reached the distal tip of the imaging guidewire, it positional relationship between the imaging components and the working head remains unchanged during operation and that the catheter and the guidewire are configured to cross the lesion together by advancing the catheter together with the distal tip of the guidewire in the lumen.

While continuing to traverse the Examiner's rejections, the Applicant, in order to expedite the prosecution of the instant application, has chosen to amend claims 1 and 16 to include the limitation that at least a portion of the distal tip having a diameter that is larger than a rest of the guidewire having a smaller diameter. Applicant contends that such amendment clearly distinguishes the present invention over the prior art of record. Support for the amendment may be found in the drawings and specification of the instant application as referenced above.

Further, in order to clarify the relationship between the working head and the imaging guidewire, claims 1 and 16 have been amended to recite that "when said catheter reaches said distal tip of said guidewire at least a portion of said imaging components are positioned inside said working head and a portion of said distal tip is the only element of either of said imaging guidewire and said catheter extending in front of said working head." Applicant points out that the amendment is merely a rephrasing of the current claim language and therefore, support for the amendment may be found throughout the specification and drawings of the instant application.

As discussed with the Examiner in the above mentioned Telephone Interview, Applicant asserts that an imaging guidewire in which the distal tip that houses at least some of the imaging components is novel. Therefore, new claims 33 and 34 in which the sole novel feature is the relation ship of the diameter of the distal tip of the imaging

guidewire to the diameter of the rest of the length of the imaging guidewire have been added. New claim 33 recites the limitations of claim 16 with the exception of the distal tip extending in front of the working head. New claim 34 is directed solely toward an imaging guidewire in which at least a portion of the distal tip has a diameter that is larger than a rest of the guidewire which has a smaller diameter. Dependent claims 35-37 are directed toward further limitations supported by the specification and the drawings.

Applicant asserts that there is neither hint nor suggestion in the cited prior art to provide the combination of imaging guidewire and working head as now claimed.

The Applicant believes that the above comments and amendments completely overcome the Examiner's rejections of claims 1 and 16 on §103(a) grounds, and therefore the rejections of claims 2-15 and 17-31, which depend therefrom, are now rendered moot.

In view of the above remarks, it is respectfully submitted that the claims are in condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
DR. MARK FRIEDMAN, LTD

By _____

Mark M. Friedman
Attorney for Applicant
Registration No. 33,883